U.S. Food and Drug Administration

Generic Drug User Fee Amendments of 2012

Communications Between Industry and FDA

LCDR Linda Park
CDER Office of Generic Drugs
U.S. Food and Drug Administration

Disclaimer & Disclosure

- View presented are those of the speaker and do not reflect official FDA, HHS or other government opinion or policy.

- I have nothing to disclose.

Learning Objectives

- Point of Contact for Industry and FDA
- 356h Form and Cover Letters
- Patent & Exclusivity Amendment Submissions
- Other Helpful Communication Issues

Point of Contact for Industry and FDA

- Applicants should designate one Point-of-Contact (POC) when interacting with FDA.
- Applicants should contact the designated OGD Regulatory Project Manager (RPM) as RPM is the primary POC for all questions related to ANDAs and supplements.
- When calling or emailing the RPM, state the nature of the contact.
  - ANDA, PAS, CBE, DMF, patent expiration date, forfeiture date, and etc.?

Point of Contact for Industry and FDA

- Please do not contact individual reviewers, team leaders, directors (includes not ccing them on emails).

- Applicants will know who to contact based on the *filing acceptance letter* or *CR Letter*.

356h Form and Cover Letters

- Every 356h should have the following:
  - Updated **Applicant** and **U.S. Agent** phone and fax numbers.
  - Responsible **Official/Agent's** updated phone & fax numbers, email.

356h Form

Food and Drug Administration

APPLICATION TO MARKET A NEW OR ABBREVIATED NEW DRUG OR BIOLOGIC FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Expiration Date: December 31, 2013
See PRA Statement on page 3.

1. Date of Submission *(mm/dd/yyyy)*: 10/28/2013

APPLICANT INFORMATION

2. Name of Applicant: GENERIC DRUGS LIMITED

3. Telephone Number *(Include country code if applicable and area code)*: 91-40-12345678/12

4. Facsimile (FAX) Number *(Include country code if applicable and area code)*: 91-40-87654321

5. Applicant Address

Address 1 *(Street address, P.O. box, company name c/o)*: (HELP ME Unit I in Happy Valley)

Address 2 *(Apartment, suite, unit, building, floor, etc.)*: Generic Drug Village, Building 1000

City: Pharmaceutical City

State/Province/Region: Region All Naturale

Country: My Country

ZIP or Postal Code: 123 456

Email Address: helpme@mycountry.com

U.S. License Number if previously issued:

6. Authorized U.S. Agent *(Required for non-U.S. applicants)*

Authorized U.S. Agent Name: Dr. I'm Somebody, Director-Regulatory Affairs

Address 1 *(Street address, P.O. box, company name c/o)*: Generic Drugs USA, Inc.,

Address 2 *(Apartment, suite, unit, building, floor, etc.)*: 123 Generic Drug Avenue

City: Generics City

State: New Jersey

ZIP Code: 12345

Telephone Number *(Include area code)*: 732-123-4567

FAX Number *(Include area code)*: 732-765-4321

Email Address: imsomebody@genericdrugsusa.com

PRODUCT DESCRIPTION

7. NDA, ANDA, or BLA Application Number

8. Supplement Number *(If applicable)*

356h Form and Cover Letters

- Every Cover Letter should have the following:
  - Clearly state what the submission entails (Minor Amendment – Final Approval Requested, Patent Amendment, etc).
  - Cover letters should NOT include titles reflecting review disciplines if they are simply acknowledging there are no comments (ex. BE) in response to a CR Letter.

A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

RESUBMISSION
1st/2nd/3rd/4th/5th (if GDUFA) MINOR / MAJOR (TIER 1, 3)
COMPLETE RESPONSE
CHEMISTRY / BIOEQUIVALENCE / CLINICAL / MICROBILOGY / LABELING

Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the ANDA under 21 CFR 314.65. You may also request an extension of time in which to resubmit the ANDA. A resubmission response must fully address all the deficiencies listed.

The drug product may not be legally marketed until you have been notified in writing that this ANDA is approved.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

APPLICATION INFORMATION

16. Application Type *(Select one)*
- ☐ New Drug Application (NDA)
- ☐ Biologics License Application (BLA)
- ☑ Abbreviated New Drug Application (ANDA)

17. If an NDA, identify the type ☐ 505 (b)(1) ☐ 505 (b)(2)

18. If a BLA, identify the type ☐ 351 (a) ☐ 351 (k)

19. If a 351(k), identify the biological reference product that is the basis for the submission.

Name of Biologic: _____ Holder of Licensed Application: _____

20. If an ANDA, or 505(b)(2), identify the listed drug product that is the basis for the submission.

Name of Drug: ABC Capsules, 10 mg Application Number of Relied Upon Product: 123456

Indicate Patent Certification(s): ☐ P1 ☐ P2 ☑ P3 ☐ P4 ☐ Section viii - MOU ☐ Statement of no relevant patents

21. Submission *(Select one)* ☑ Original ☐ Labeling Supplement ☐ CMC Supplement ☐ Efficacy Supplement ☐ Annual Report
☐ Product Correspondence ☐ REMS Supplement ☐ Postmarketing Requirements or Commitments ☐ Periodic Safety Report
☐ Other *(Specify)*: _____

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22. Submission Sub-Type ☐ Presubmission ☐ Amendment ☐ Initial Submission ☑ Resubmission

23. If a supplement, identify the appropriate category. ☐ CBE ☐ Prior Approval (PA) ☐ CBE-30

24. Does this submission contain *only* pediatric data? ☐ Yes ☑ No

25. Reasons for Submission

Resubmission 1st Minor (Tier 1) Complete Response- Chemistry/Labeling

26. Proposed Marketing Status *(Select one)* ☑ Prescription Product (Rx) ☐ Over-The-Counter Product (OTC)

27. This application is *(Select one)* ☐ Paper ☐ Paper and Electronic ☑ Electronic

28. Number of Volumes Submitted NA

356h Form and Cover Letters

- Every Cover Letter should also reflect the following:

  - State clearly in the cover letter any review discipline that contains new data that is outside of the CR response to the CR Letter.

A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission:

RESUBMISSION
1st/2nd/3rd/4th/5th (if GDUFA) MINOR / MAJOR (TIER 1, 3)
COMPLETE RESPONSE
CHEMISTRY / BIOEQUIVALENCE / CLINICAL / MICROBILOGY / LABELING

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356h Form and Cover Letters

- When responding to CR Letters:

> Within one year after the date of this letter, you are required to resubmit or take other actions available under 21 CFR 314.110. If you do not take one of these actions, we may consider your lack of response a request to withdraw the ANDA under 21 CFR 314.65. You may also request an extension of time in which to resubmit the ANDA. A resubmission response must fully address all the deficiencies listed.

356h Form and Cover Letters

- Cover Letters should state the following <u>if applicable</u>:
  - State **Expedited Review Requested** –or-
  - State **Expedited Review Granted**
  - **Drug Shortage**, **PEPFAR**

356h Form and Cover Letters

Extremely Important

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, registration number (FEI), MF number, Establishment DUNS number, and manufacturing steps and/or type of testing (e.g., final dosage form, stability testing, container closure) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

***All facilities involved must be submitted**. For supplements, all new sites, **as well as all previously approved sites (even inactive and withdrawn ones)** should also be included. New sites are to be flagged as "pending".*

29 Establishment Information *(Full establishment information should be provided in the body of the application.)*

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, registration number (FEI), MF number, Establishment DUNS number, and manufacturing steps and/or type of testing (e.g., final dosage form, stability testing, container closure) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Establishment Name
GENERIC DRUGS LIMITED UNIT 10

Address 1 *(Street address, P.O. box, company name c/o)*
Generic Drug Village, Building 1000

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
Pharmaceutical City

State/Province/Region
Region All Naturale

Country
My Country

ZIP or Postal Code
123 456

Registration (FEI) Number
9871236549

MF Number

Establishment DUNS Number
987654321

Is the establishment new to the application? ☐ Yes ☑ No

What is the status of the establishment? ☐ Pending ☑ Active ☐ Inactive ☐ Withdrawn

Establishment Contact Information

Name of Contact for the Establishment
Dr. Imake Good Drugs, Director (Pharma)

Address 1 *(Street address, P.O. box, company name c/o)*
GENERIC DRUGS LIMITED UNIT 10

Address 2 *(Apartment, suite, unit, building, floor, etc.)*
Generic Drug Village, Building 1000

City
Pharmaceutical City

State
Region All Naturale

ZIP or Postal Code

Telephone Number *(Include area code)*
91-40-12345678

FAX Number *(Include area code)*
91-40-87654321

Email Address
imakegooddrugs@genericdrugslimited.com

Manufacturing Steps and/or Type of Testing
Manufacturing Steps and/or Type of Testing: All steps of finished dosage form manufacturing and packaging. Testing of of finished dosage form including in-process, finished dosage and stability testing .

Is the site ready for inspection? ☑ Yes ☐ No
If No, when will site be ready? *(mm/dd/yyyy)*

Continuation Page for #29

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to, the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state, and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

32. Typed Name and Title of Applicant's Responsible Official	33. Date *(mm/dd/yyyy)*
Dr. I'm Somebody, Director-Regulatory Affairs	10/28/2013

34. Telephone Number *(Include country code if applicable and area code)*	35. FAX Number *(Include country code if applicable and area code)*	36. Email Address
732-529-0423	732-562-8854	imsomebody@genericdrugsusa.com

37. Address of Applicant's Responsible Official

Address 1 *(Street address, P.O. box, company name c/o)*		
Generic Drugs USA, Inc.		
Address 2 *(Apartment, suite, unit, building, floor, etc.)*		
123 Generic Drug Avenue		
City	State/Province/Region	
Generics City	New Jersey	
Country	ZIP or Postal Code	
United States of America	12345	

38. Signature of Applicant's Responsible Official or Other Authorized Official	39. Countersignature of Authorized U.S. Agent
Sign	Sign

Patent & Exclusivity Amendment Submissions

- ANDAs going from TA to Full Approval, submit full patent and exclusivity summary, supporting documentation, and court case outcomes, etc.

- Prior to Full Approval, FDA needs **up to date** report on the status of any on-going litigation.

Patent & Exclusivity Amendment Submissions

- FDA needs the **final order** from the court whether it's a dismissal or a decision.

- A *proposed* order is not helpful because it is NOT finalized, especially when a case may be dismissed.

Patent & Exclusivity Amendment Submissions

- Firms should submit to the ANDA and inform the RPM directly by phone/email as well, of any specific date the ANDA will need to be TA'd/AP'd to give a heads up (forfeiture date, patent expiry).

- Request for Final Approval Minor Amendment should be at least 90 days out from Final Approval (per TA Letter).

Other Helpful Communication Issues

- Any unsolicited change under GDUFA *adjusts* the GDUFA review goals.

- Requests for TA to Full Approvals. Changes can delay your full approval.

Other Helpful Communication Issues

- FDA will provide general ANDA status inquiries.

- Discipline specific information will be communicated when a CR Letter is issued.

Other Helpful Communication Issues

- RPM contact information is on all CR Letters. If it has changed, inquire who is the current RPM point-of-contact.

- Submit electronic copies to the Gateway of ALL submissions, no matter how short or long. This includes general correspondences, patent amendments, etc.

Other Helpful Communication Issues

- Again: be specific as possible in titles on cover letters, e.g., **Transfer of Ownership**, **Change of U.S. Agent**, **Patent Amendment**, etc.

- All documents need to be submitted electronically via the Gateway following the eCTD format for GDUFA metric goals to apply.

Other Helpful Communication Issues

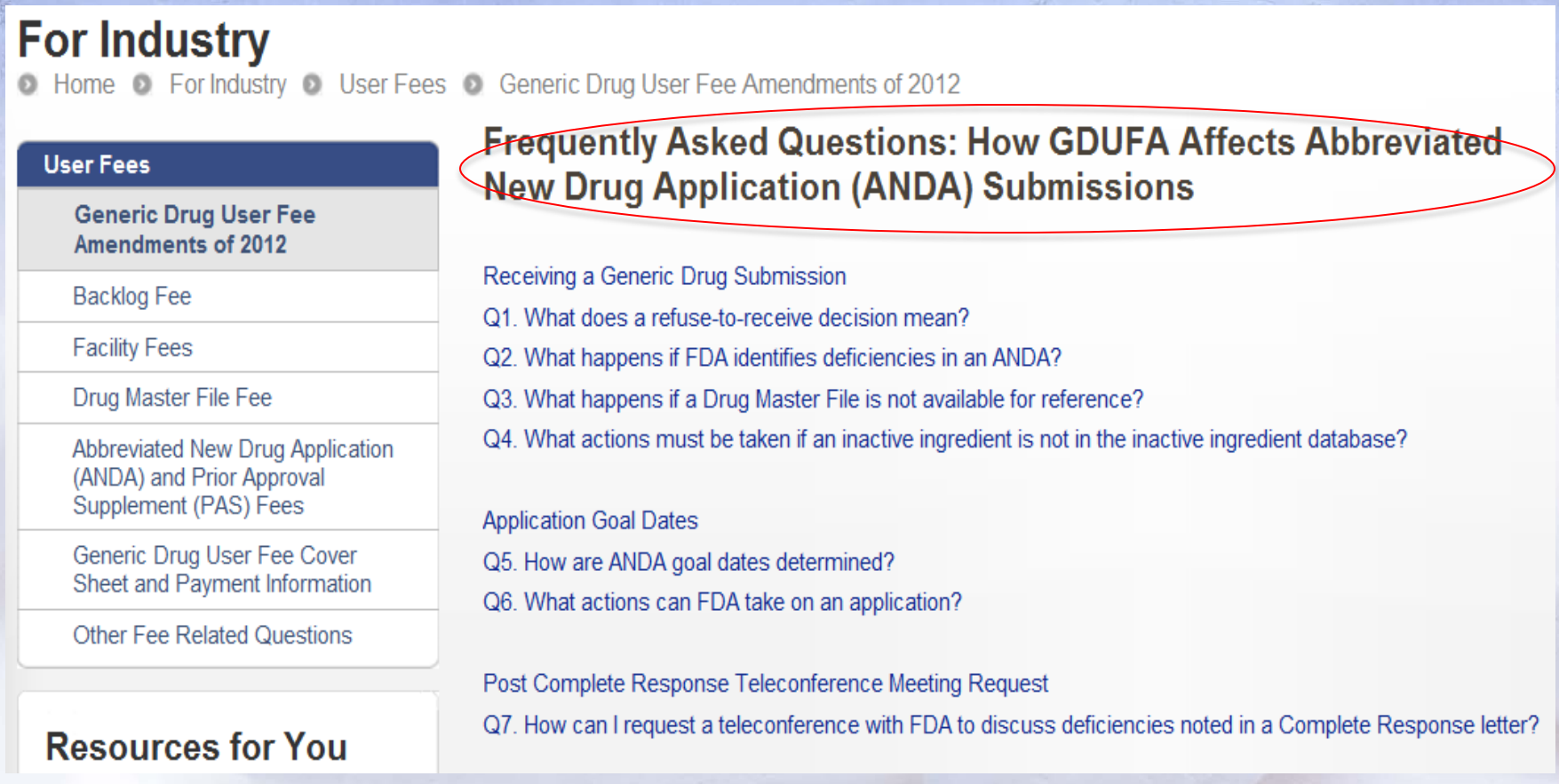
- Stay Tuned . . . Guidances for Industry will be forth coming to improve communication between Industry and FDA, provide greater transparency, and assist both Industry and FDA in GDUFA's implementation.
- OGD Policy Office drafting Guidances for Industry.

Resources

Contact Information:

- For general GDUFA questions: AskGDUFA@fda.hhs.gov
- For user fee questions: CDERCollections@fda.hhs.gov
- For questions about Drug Master Files: OGDDMF@fda.hhs.gov
- Sign Up for Email Alerts on GDUFA

Resources



http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm385694.htm